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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,380	07/12/2006	Joshua Shua-Haim	PN/4-33146A	3361

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EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,380	SHUA-HAIM ET AL.	
	Examiner	Art Unit	
	CARLIC K. HUYNH	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-10 and 12* is/are pending in the application.

4a) Of the above claim(s) *6-10 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :21 September 2005, 19 December 2007, and 07 January 2008.

DETAILED ACTION

Status of the Claims

1. Claims 5-10 and 12 are pending in the application, with claims 6-10 and 12 having been withdrawn from consideration, in response to the restriction requirement submitted on November 1, 2007. Accordingly, claim 5 is being examined on the merits herein. retrieved

Election/Restrictions

2. Applicant's election without traverse of the claims of Group I, namely claims 5-8, in the reply filed on December 5, 2007 is acknowledged.

Claims 9-10 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on December 5, 2007.

3. Applicants' election of: (1) a compound of Formula I, wherein R_1 and R_2 are hydroxy as the compound of Formula I; and (2) agitation as the disease state in the reply filed on December 5, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

During a telephone conversation with Kristin Nevins on February 21, 2008, a provisional election was made without traverse to elect the species of a compound of Formula I wherein R_1 is hydrogen and R_2 is hydroxy in claims 5-8. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 6-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on December 5, 2007.

Accordingly, claim 5 is examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statements submitted on September 21, 2005, December 19, 2007, and January 7, 2008, are acknowledged.

Specification

4. The use of the trademarks Ginkodilat™, Cinnarizin forte-ratiopharm™, Nimotop™, Aricept™, Exelon™, Reminyl™, Hydergin™, Sermion™, Cerebroforte™, Cosaldon™, Encephabol™, and Cavinton™ have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a method of treatment for Alzheimer's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to a method for the treatment of Alzheimer's disease.

(2). ***State of the Prior Art***:

The skilled artisan would view that there is no effective treatment to reverse, slow down, or prevent Alzheimer's disease (see page 487 of Drugs Aging, 2002, Vol. 19, No. 7, pp. 487-

494).

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the art of Alzheimer's disease is extremely high.

(4). ***Predictability of the Art***:

Any treatment for Alzheimer's disease is highly unpredictable. In fact, Alzheimer's disease is well known to be a complex multi-causal disease of unknown etiology. Moreover, according to Vickers, there is no effective treatment to reverse, slow down, or prevent Alzheimer's disease (see page 487 of Drugs Aging, 2002, Vol. 19, No. 7, pp. 487-494). It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass a method for the treatment of Alzheimer's disease.

(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to effectively treat Alzheimer's disease is limited (pages 2-3 of the specification).

(7). ***Working Examples***:

The working examples in the specification show treatment of patients diagnosed with Alzheimer's disease with oxcarbazepine.

However, according to Vickers, there is no effective treatment to reverse, slow down, or prevent Alzheimer's disease (page 487 of Drugs Aging, 2002, Vol. 19, No. 7, pp. 487-494). Moreover, Vickers disclose there are pharmaceutical interventions available that improve certain symptoms in the subset of affected individuals for a short period of time, but ultimately all cases follow the same progressive and degenerative path to severe dementia (page 487).

Therefore, the invention may not work with all methods for treating Alzheimer's disease herein claimed.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support for a method of treatment for Alzheimer's disease. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any treatment of Alzheimer's disease having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without ***undue experimentation***.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "agitation", and the claim also recites "behavioral agitation" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

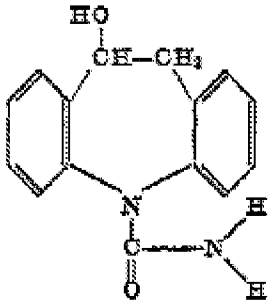
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Schindler (US 3,637,661). Examiner cites of interest the "epilepsy" entry (http://www.merriam-webster.com/dictionary/epilepsy) and the "agitation" entry (http://www.merriam-webster.com/dictionary/agitation).

Claim 5 is directed at a method for the treatment of a disease selected from the group consisting of agitation, behavioral agitation and Alzheimer's disease. Given the broadest reasonable interpretation of the instant claim 5, agitation is generic. Thus any disease where a characteristic of the disease includes agitation would anticipate applicant's invention. Epilepsy is well known in the art to be a disorder manifested by seizure activity, including agitation. Moreover, Examiner cites "Epilepsy" is defined in the art as a disorder manifested by sudden brief episodes of altered or diminished consciousness, involuntary movements, or convulsions (http://www.merriam-webster.com/dictionary/epilepsy).

Schindler teaches a method of treating epilepsy comprising administering a compound of the formula,



(abstract; and column 1, lines 29-38).

Again, Examiner cites of interest "Epilepsy" is defined in the art as a disorder manifested by sudden brief episodes of altered or diminished consciousness, involuntary movements, or convulsions (http://www.merriam-webster.com/dictionary/epilepsy). Examiner further cites of interest "Agitation" is defined in the art as a movement with an irregular, rapid, or violent action (http://www.merriam-webster.com/dictionary/agitation). Thus the convulsions of epilepsy can be a form of agitation. Since Schindler teach a method of treating agitation, Schindler anticipates the Applicant's invention.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

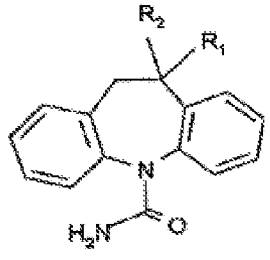
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 5 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application Martenyi et al. (10/550,382). Examiner cites of interest the "affective disorder" entry (http://www.britannica.com/eb/article-9003908/affective-disorder).

Claim 5 is directed at a method for the treatment of a disease selected from the group consisting of agitation, behavioral agitation and Alzheimer's disease. Given the broadest reasonable interpretation of the instant claim 5, agitation is generic. Thus any disease where a characteristic of the disease includes agitation would anticipate applicant's invention.

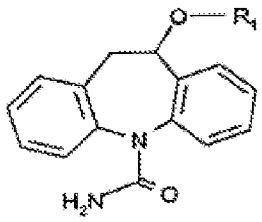
The instant claim is directed to a method of treating agitation comprising administering a compound of formula I,



,

where R_1 is hydrogen and R_2 is hydroxyl.

The claims of Martenyi et al. are directed to a method of treating affective disorders comprising administering a compound of formula I,



,

where R_1 is hydrogen. Examiner cites of interest "Affective disorder" is defined in the art as a mental disorder characterized by changes or extremes of mood and may include manic and depressive episodes and that the depressive episode may be a dejected mood with agitation (http://www.britannica.com/eb/article-9003908/affective-disorder). Thus affective disorders are a species of the generic set of diseases defined by "agitation". The claims of Martinyi et al. are obvious over the instant claim 5 because the method of treating an affective disorder is the same as a method of treating agitation and because the compound of formula I in the conflicting applications are identical when R_1 of Martenyi is hydrogen and R_1 is hydrogen and R_2 is hydroxy in the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

ckh